## CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-180

MICROBIOLOGY REVIEW(S)

# Review for Division of Reproductive and Urologic Drug Products, HFD-580 Office of New Drug Chemistry, Microbiology Staff, HFD-805 Microbiologists's Review No. 1

March 30, 2001

MICROBIOLOGY REVIEWER: Carol K. Vincent

A. 1. NDA No.: 21-180

DRUG PRODUCT NAME: Ortho-Evra [norelgestromin/ethinyl estradiol]

APPLICANT: R.W. Johnson Pharmaceutical Research Institute

920 Route 202 South

PO Box 300

Raritan, New Jersey 08869-0602

2. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Transdermal patch.

3. METHOD(s) OF STERILIZATION: Non-sterile patch.

- 4. PHARMACOLOGICAL CATEGORY AND/OR PRINCIPAL INDICATION: Contraceptive.
- 5. DRUG PRIORITY CLASSIFICATION: 1 S
- B. 1. DOCUMENT DATE: December 21, 2000
  - 2. DOCUMENT RECEIVED FOR REVIEW: February 9, 2001
  - 3. COMIS USER FEE DUE DATE: June 19, 2001
- C. REMARKS: The Division requested review of the validation of the Microbial Limits Test, USP.
- D. CONCLUSION and RECOMMENDATION:

Recommend **approval** for subject drug product for microbiological quality. **COMMENTS** regarding certain issues in the microbial limits testing should be supplied to the applicant.

See "E: Review Notes" and "COMMENTS to be supplied to applicant", below.

CC:

Orig. NDA 21-180

HFD-160/Consult/CKVincent [HFD-805]

HFD-580/Wu/Mercier

Drafted by: CKVincent/02-12-2001 Revised by: CKVincent/03-30-2001

Filename: '

Carol K. Vincent

Review Microbiologist [HFD-805]

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# THIS SECTION WAS DETERMINED NOT TO BE RELEASABLE

2 pages

#### ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

FDA CDER EES

Application:

NDA 21180/000

Priority: S

Org Code: 580

Stamp: 21-DEC-2000 Regulatory Due: 21-OCT-2001

Action Goal:

District Goal: 22-AUG-2001

Applicant:

**JOHNSON RW** 

Brand Name:

920 RT 202 SOUTH

**RARITAN, NJ 088690670** 

**EVRA(NORELGESTROMIN/ETHINYL** 

**ESTRAD** 

ORTHO

Established Name:

Generic Name: NORELGESTROMIN/ETHINYL

**ESTRADIOL** 

Dosage Form:

FLM (TRANSDERMAL SYSTEM)

Strength:

NRG/EE (150/20 MCG/DAY)

FDA Contacts:

A. MITRA

(HFD-580)

301-827-4238 , Review Chemist

Overall Recommendation:

ACCEPTABLE on 11-OCT-2001 by M. GARCIA (HFD-322) 301-594-0095

Establishment:

MF No:

AADA No:

Profile: CTL

OAI Status: NONE

Responsibilities:

Last Milestone: OC RECOMMENDATION

Milestone Date: 26-MAR-2001

**ACCEPTABLE** 

Decision: Reason:

**BASED ON PROFILE** 

Establishment:

DMF No:

AADA No:

Profile: CTL

OAI Status: NONE

Responsibilities:

Last Milestone: OC RECOMMENDATION

Milestone Date: 04-JUN-2001

Decision:

**ACCEPTABLE** 

Reason:

DISTRICT RECOMMENDATION

Establishment:

DMF No: -

AADA No:

Profile: CSN

OAI Status: NONE

Responsibilities:

Last Milestone: OC RECOMMENDATION

Milestone Date: 09-APR-2001

## FDA CDER EES ESTABLISHMENT EVALUATION REQUEST **SUMMARY REPORT**

Decision: Reason:	ACCEPTABLE DISTRICT RECOMMENDATION			
Establishment:		DMF No:	·	
	OAI Status: NONE OC RECOMMENDATION 27-MAR-2001 ACCEPTABLE DISTRICT RECOMMENDATION	Responsibilities:		
Establishment:		OMF No: ADA No:		St. Co.
	OAI Status: NONE OC RECOMMENDATION 02-MAY-2001 ACCEPTABLE DISTRICT RECOMMENDATION	Responsibilities:		
Establishment:		DMF No: AADA No:		
	QAI Status: NONE OC_RECOMMENDATION 26-MAR-2001 ACCEPTABLE BASED ON PROFILE	Responsibilities:		
Establishment:		DMF No: ( AADA No:		
Profile: CTL	OAI Status: NONE	Responsibilities:		

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## FDA CDER EES ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

	OC RECOMMENDATION  26-MAR-2001  ACCEPTABLE  BASED ON PROFILE		TESTER
Establishment:	2211100 ORTHO PHARMACEUTICAL CORP 1000 RTE 202 RARITAN, NJ 08869	DMF No: AADA No:	
Profile: CTL Last Milestone: Milestone Date Decision: Reason:	OAI Status: NONE OC RECOMMENDATION 09-JUL-2001 ACCEPTABLE DISTRICT RECOMMENDATION	Responsibilities:	DRUG SUBSTANCE RELEASE TESTER DRUG SUBSTANCE STABILITY TESTER
Establishment:	2242831 ORTHO PHARMACEUTICAL CORP NUMBER I CAMPUS DR SOMERSET, NJ 08873	DMF No: AADA No:	· <b>3</b>
	OAI Status: NONE OC RECOMMENDATION 03-MAY-2001 WITHHOLD FACILITY NOT DOING FUNCTION	Responsibilities:	FINISHED DOSAGE OTHER TESTER
Establishment:	ORTHO-MCNEIL PHARMACEUTICA 701 GALVESTON DRIVE REDWOOD CITY, CA 94063	DMF No: AADA No:	
Milestone Date:	OAI Status: NONE OC RECOMMENDATION 09-OCT-2001 ACCEPTABLE DISTRICT RECOMMENDATION	Responsibilities:	FINISHED DOSAGE MANUFACTURER FINISHED DOSAGE STABILITY TESTER

Establishment:

DMF No:

AADA No:

Profile: TDP

OAI Status: NONE

Responsibilities:

## FDA CDER EES **ESTABLISHMENT EVALUATION REQUEST** SUMMARY REPORT

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Last Milestone: OC RECOMMENDATION

Decision:

Milestone Date: 07-MAY-2001 **ACCEPTABLE** 

Reason:

DISTRICT RECOMMENDATION

APPEARS THIS WAY ON ORIGINAL

# ORTHO EVRA® (norelgestromin/ethinyl estradiol) Transdermal Patch

R.W. Johnson Pharmaceutical Research Institute 1, 4S

PM: Jennifer Mercier HFD-580 7-4260

Submission Date: December 21, 2000 Primary Goal Date: October 21, 2001 Secondary Goal Date: December 21, 2001

**Methods Validation** 

Methods have not yet been validated.

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